

## REMARKS

Reconsideration is requested. Claims 1-12 are pending. For reasons to be set forth in detail below, it is respectfully submitted that the present application is in condition for allowance, and such action is requested.

Independent claims 1, 5 and 10 have been amended to clarify the presently claimed subject matter.

### 35 U.S.C. §112 Rejections

The subject matter of claims 1-12 was rejected under 35 U.S.C. §112, second paragraph, as indefinite. In particular, it was noted that claim's recitation of "covering the receiving aperture" was confusing. It was suggested in the prior Office Action that the claims recite that the reagent pad covers the bottom surface of the aperture. Accordingly, independent claims 1, 5, and 10 have been amended to recite that the reagent pad is "underlying" the aperture (support at, for example, page 3, lines 19-20 and FIGs. 2 and 3 of the disclosure). Therefore, Applicants respectfully submit that claims 1-12, as amended, are allowable under 35 U.S.C. §112.

### 35 U.S.C. §102 Rejections:

The subject matter of claims 1, 2 and 10 was rejected in the prior Office Action under 35 U.S.C. §102(e) as anticipated by U.S. Patent No. 6,299,838 to Hirayama et al., (hereinafter "Hirayama").

Hirayama, as understood, describes a test apparatus that includes a cover (e.g., cover 5) with a sample-supplying hole (e.g., hole 51), a reagent layer (e.g., layer 3), and a support (e.g., support 1) with a measurement hole (e.g., hole 11) therethrough (see, for example, col. 3, lines 29-55; col. 5, lines 56-60 and FIGs. 1-3 of Hirayama). Gravity flow and capillary action serve to transfer a sample from the sample-supplying hole to the reagent layer via a sample-holding room 4 (see, for example, col. 5, line 60 through col., 6, line 5 and FIG. 1 of Hirayama).

Applicants respectfully note that the following: (a) the reagent layer described in Hirayama covers the measurement hole and underlies the cover but does not underlie the sample-supplying hole; and (b) Hirayama distinguishes the cover from the support.

Independent claims 1 and 10, as amended, each recite the presence of “a reagent pad affixed to the support and **underlying** the sample receiving aperture” (emphasis added). In addition, independent claims 1 and 10 recite that a portion of the support’s bottom surface “surrounding the aperture has a reflectivity of less than about 12 percent at between about 600 and 730nm” and that that portion, along with the aperture, correspond to an optical viewing area of an associated meter (claim 1) or colorimeter (claim 10).

Hirayama does not describe, teach or suggest a reagent layer that underlies a sample receiving aperture. Rather Hirayama describes and teaches that the reagent layer cover a measurement hole, **underlie a cover**, and be is spaced away from a sample-supplying hole by a sample holding room (see discussion above and FIG. 1 of Hirayama). In addition, although Hirayama teaches that a cover may be colored, it does not describe, teach or suggest that a support’s bottom surface “surrounding the aperture has a reflectivity of less than about 12 percent at between about 600 and 730nm” and that that portion, along with the aperture, correspond to an optical viewing area of an associated meter (claim 1) or colorimeter (claim 10).

For at least the foregoing reasons, Applicants submit that the subject matter of amended claims 1 and 10 is neither anticipated not obvious over Hirayama and allowable under 35 U.S.C. §102(e). Since dependent claims necessarily contain the limitations of their parents, dependent claim 2 is allowable for at least the same reasons.

### 35 U.S.C. §103 Rejections

The subject matter of dependent claims 3 and 11 was rejected in the prior Office Action under 35 U.S.C. §103(a) as obvious over Hirayama. Since dependent claims necessarily contain the limitations of their parents, dependent claims 3 and 11 are allowable for at least the same reasons as discussed above with respect to independent claims 1 and 10.

The subject matter of claims 3-9 and 11 was rejected in the prior Office Action under 35 U.S.C. §103(a) as obvious over Hirayama in view of U.S. Patent No. 5,843,692 to Phillips et al. (hereinafter "Phillips").

Phillips, as understood, describes a glucose assay device in the form of a strip with a reagent pad, hole and notch (see, for example, col. 9, line 44; col. 10, lines 61-65 and col. 11, lines 15-16 of Phillips). Phillips was cited for sample volume and notch teachings.

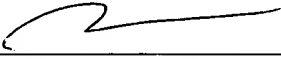
Independent claim 5 recites that an aperture and portion of a bottom surface of a support correspond to an optical viewing area of a measuring instrument. As explained above with respect to claims 1 and 10, Hirayama does not describe, teach or suggest such a configuration. Phillips does not appear to cure this deficiency. Applicants, therefore, respectfully submit that the subject matter of amended claim 5 is not obvious over the cited combination of Hirayama and Phillips and is allowable under 35 U.S.C. §103(a).

Since claims 3-4, 6-9 and 11 depend from and further limit independent claims 1, 5 and 10, respectively, they are patentable for at least the same reasons.

### CONCLUSION

Applicants respectfully request that, in light of the amendments and explanations above, the Examiner reconsider and withdraw his rejections. Applicants respectfully submit that the claims are in condition for allowance. In the event that minor claim amendments are necessary to meet formal requirements, Applicants invite the Examiner to telephone the undersigned so that issuance can be expedited.

Respectfully submitted,

By:  3/26/04  
Mayumi Maeda  
Reg. No. 40,075  
Attorney for Applicant

Johnson & Johnson  
International Patent Law Division  
Attention: Philip Johnson  
P.O. Box 1222  
New Brunswick, NJ 08903  
Date: 03-29-2004